

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: GADOLINIUM BASED CONTRAST
AGENTS PRODUCTS LIABILITY
LITIGATION

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Case No. 1:08 GD 50000

MDL No. 1909

Judge Dan Aaron Polster

CINDY TORRES, individually and as the duly
appointed Administrator of the Estate of her
Husband, GEORGE TORRES; GEORGE SCOTT
TORRES, an individual; KEVIN TORRES, an
individual; and TIMOTHY RYAN TORRES, an
individual,

Plaintiffs,

v.

GENERAL ELECTRIC COMPANY;
GE HEALTHCARE AS;
GE HEALTHCARE INC.;
BAYER HEALTHCARE
PHARMACEUTICALS INC.,

Defendants.

COMPLAINT AND JURY DEMAND

Plaintiff Cindy Torres, an individual and as the duly appointed Administrator of the
Estate of her Husband, George Torres, Deceased; George Scott Torres, an individual; Kevin
Torres, an individual; and Timothy Ryan Torres, an individual, through Undersigned Counsel
and for their Complaint against the defendants, allege upon information and belief as follows:

I. BASIS FOR CAUSES OF ACTION

1. Plaintiffs bring this action to recover for the wrongful death caused as a direct and proximate result of their husband/father's exposure to gadolinium through administration of the gadolinium-based contrast agents, Omniscan and Magnevist, as designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants herein.

II. PARTIES

A. PLAINTIFFS

2. Plaintiff **CINDY TORRES** is and was at all times relevant to the allegations herein a resident and citizen of Pueblo County, Colorado. At all relevant times, she was the wife of George Torres.

3. Decedent **GEORGE TORRES** was at all times relevant a resident and citizen of Pueblo County, Colorado.

4. Plaintiff Cindy Torres' husband, George Torres, died on August 26, 2008 in Pueblo County, Colorado.

5. Plaintiff **GEORGE SCOTT TORRES** is and was at all times relevant a resident of Pueblo County, Colorado and the son of Cindy and George Torres.

6. Plaintiff **KEVIN TORRES** is and was at all times relevant a resident of Pueblo County, Colorado and the son of Cindy and George Torres.

7. Plaintiff **TIMOTHY RYAN TORRES** is and was at all times relevant a resident

of Pueblo County, Colorado and the son of Cindy and George Torres.

B. DEFENDANTS

OMNISCAN:

8. **GENERAL ELECTRIC COMPANY** is a New York Corporation with its principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06431. General Electric Company is a resident of both New York and Connecticut and is the parent company of Defendants GE Healthcare AS and GE Healthcare, Inc. Service of process may be had by serving its Registered Agent for service, CT Corporation System, One Corporate Center, Floor 11, Hartford, CT 06103.

9. Omniscan, one of the products in question in this suit, is identified by General Electric Company in its packaging that it is a product of "GE Healthcare," which is a unit/division of General Electric Company. "GE Healthcare" is prominently identified on the Omniscan packaging/prescribing information, alongside the "GE" monogram. Omniscan is identified as a trademark of GE Healthcare. "GE" and the GE monogram are trademarks of the General Electric Company. The GE Healthcare website, which includes detailed product information concerning Omniscan, is copyrighted by General Electric Company. General Electric Company does business as GE Healthcare, including the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce the drug Omniscan.

10. At all times relevant, Defendant General Electric Company, and/or its corporate predecessors, were engaged in the business of designing, licensing, manufacturing, distributing,

selling, marketing, and/or introducing into the stream of commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

11. **GE HEALTHCARE AS** is a Norwegian corporation with its principal place of business in the Kingdom of Norway. GE Healthcare AS is a subsidiary of General Electric Company and admits to being the manufacturer of the Omniscan that is distributed, marketed, and sold in the United States.

12. GE Healthcare AS has agreed that GE Healthcare Inc. may accept service of process on their behalf and agrees to accept service of documents in English, waiving any defenses or objections based upon the Hague Convention for process.

13. At all times relevant, Defendant GE Healthcare AS, and/or its corporate predecessors, were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

14. **GE HEALTHCARE INC.** is a Delaware corporation with its principal place of business at 101 Carnegie Center, Princeton, New Jersey. GE Healthcare Inc. is a resident and citizen of both Delaware and New Jersey and is a subsidiary of General Electric Company. Service of process may be had by forwarding the Summons and Complaint to GE Healthcare Inc.'s Chief Executive Officer at its principal place of business at 101 Carnegie Center, Princeton, New Jersey. GE Healthcare Inc. admits to distributing, marketing, and selling Omniscan in the United States.

15. At all times relevant, Defendant GE Healthcare Inc., and/or its corporate predecessors, were engaged in the business of designing, licensing, manufacturing, distributing,

selling, marketing, and/or introducing into interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

16. Defendants General Electric Company, GE Healthcare, GE Healthcare Inc., and GE Healthcare AS will be collectively referred to in this Complaint as the “GE Defendants.”

MAGNEVIST:

17. **BAYER HEALTHCARE PHARMACEUTICALS INC.** is a Delaware corporation with its principal place of business at 6 West Belt, Wayne, New Jersey 07470. Bayer HealthCare Pharmaceuticals Inc. is a resident and citizen of both Delaware and New Jersey. Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals unit of Schering Berlin, Inc. and is a division of Bayer AG. Service of process may be had by serving its Chief Executive Officer at its principal place of business at 6 West Belt, Wayne, New Jersey 07470.

18. Bayer HealthCare Pharmaceuticals Inc. is a corporate successor to Berlex Laboratories, Inc. (“Berlex” hereinafter) and as such is obligated for its predecessor’s liabilities. Berlex was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Magnevist.

19. Bayer HealthCare Pharmaceuticals Inc., formerly known as Berlex, Inc., formerly known as Berlex Laboratories, Inc., was engaged in the business of distributing, selling and marketing the prescription pharmaceutical Magnevist in the United States at all relevant times.

20. Defendants Bayer HealthCare Pharmaceuticals Inc., will be referred to in this Complaint as the “Bayer Defendant.”

21. At all relevant times, the Bayer Defendant were each engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agent Magnevist that was administered to Plaintiff, and/or the Bayer Defendant are otherwise responsible as corporate successors for the liabilities of the entities that designed, licensed, manufactured, distributed, sold, marketed, and/or introduced into interstate commerce the diagnostic agent Magnevist.

III. JURISDICTION

22. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

IV. FACTUAL ALLEGATIONS

A. OMNISCAN

23. Omniscan is an injectable paramagnetic contrast agent for magnetic resonance imaging and arteriography. It contains the metal gadolinium, which is highly toxic in its free state. Omniscan, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethylamide (gadodiamide), is represented by the GE Defendants to be safely and effectively

indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

24. Omniscan is cleared from the body solely by glomerular filtration in the kidneys. As a result, it has a prolonged half-life in patients with renal insufficiency who, therefore, are at increased risk for adverse health effects in connection with Omniscan administration.

25. Omniscan was originally developed by Salutar, Inc., which then conducted pre-clinical testing with Sterling Winthrop and Daiichi Pharmaceuticals. Salutar was subsequently acquired by Nycomed. In 1994, Nycomed acquired Sterling Winthrop's diagnostic imaging business.

26. In 1997, Nycomed acquired Amersham International plc, and the new company was named Amersham plc, which then held the rights to Omniscan.

27. In 2004, General Electric Company acquired Amersham plc and the rights to Omniscan. At the time of the acquisition, Amersham plc was the ultimate parent company of Amersham Health AS, which manufactured the Omniscan that was distributed and sold in the United States, and Amersham Health Inc., which distributed and sold Omniscan in the United States. In 2006, Amersham Health AS was renamed GE Healthcare AS, and Amersham Health, Inc. was renamed GE Healthcare Inc.

28. Defendants General Electric Company, GE Healthcare AS, and GE Healthcare Inc. are corporate successors to Amersham plc and its related entities and, as such, are obligated for their predecessor's liabilities. Amersham plc, either itself or by and through its subsidiaries, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce, directly and indirectly

through third parties or related entities, the drug Omniscan.

B. MAGNEVIST

29. Magnevist is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography. It contains the metal gadolinium, which is highly toxic in its free state. Magnevist, the chemical name of which is gadopentetate dimeglumine, was represented by the Bayer Defendant to be safely and effectively indicated for intravenous administration to facilitate the visualization of cranial and spinal anatomy as well as tumors, lesions, and immediately adjacent areas. Magnevist was further represented by the Bayer Defendant to be superior to two of their competitors (Omniscan and Optimark) in its thermodynamic and conditional stability, its low volume of excess chelate and its ability to prevent the release of gadolinium.

D. GENERAL ALLEGATIONS

30. At all times relevant hereto, Defendants knew, or should have known, about the significant health risk of their products' administration to patients with renal insufficiency, including, but not limited to, the risk of nephrogenic systemic fibrosis (NSF) , also known as nephrogenic fibrosing dermopathy (NFD), (collectively referred to as "NSF" hereinafter). At all times relevant hereto, Defendants knew, or should have known, that in its free state, gadolinium is highly toxic, harmful, and dangerous to humans, and causes severe physical injury; and they knew, or should have known, of the need for, among other things, proper design, testing, and manufacturing to ensure that patients using their respective products were not exposed to

gadolinium in its free state.

31. At all relevant times, Defendants knew, or should have known, that there were safer, alternative designs for paramagnetic contrast agents, such as Dotarem and other ringed chelate designs, that would prevent or minimize the risk of gadolinium becoming free in the bodies of humans, which would provide a safer imaging alternative for the public, including Decedent George Torres.

32. At all times relevant hereto, Defendants knew, or should have known, that their respective products, Omniscan and Magnevist, were not reasonably fit, suitable or safe for their intended purpose and, specifically, that they were defective and unsafe for use in patients with renal insufficiency, such as Plaintiff herein.

V. PLAINTIFF'S EXPOSURE TO GADOLINIUM

33. Decedent George Torres was a 61-year-old father with a history of end-stage renal disease. Upon information and belief, Mr. Torres was exposed to Omniscan, during imaging procedures at Memorial Health System including an MRA of lower extremity on October 4, 2005, an IR Arthroscopy on November 2, 2005, an MRA of heart/lungs on February 17, 2006, an MRA of lower extremity on July 20, 2006, an Aortogram on January 2, 2007, an MRA on March 6, 2007, and an MRA on May 11, 2007. Upon information and belief, Mr. Torres was exposed to Magnevist, during imaging procedures at Colorado Springs Imaging including an MRA of the abdomen on September 7, 2005, an MRA of the pelvis on September 7, 2005, an MRA of lower extremity on September 7, 2005, an MRA of abdomen on December 9, 2005, an MRA of pelvis on December 9, 2005, an MRA of lower extremity on December 9, 2005, an

MRA of abdomen on July 12, 2006, an MRA of pelvis on July 12, 2006, and an MRA of lower extremity on July 12, 2006.

34. After Decedent George Torres was administered the gadolinium-based contrast agent or agents, he began experiencing symptoms of NSF, including but not limited to, reddened, scaly patches of skin accompanied by severe skin pain, stiffness of the joints, and peripheral edema. He was formally diagnosed with NSF by way of punch biopsy on May 31, 2007.

35. People afflicted with NSF, such as Decedent George Torres, often spend several months or longer being examined, tested, and treated, usually by several different physicians, who attempt to establish a diagnosis. NSF can be difficult to diagnose. It is a new and rare disease that most doctors have never seen before and many NSF symptoms are also symptoms of other conditions.

36. NSF develops only in patients with renal insufficiency, such as Decedent George Torres, who have been given an injection of a gadolinium-based contrast agent such as Omniscan and/or Magnevist.

37. NSF is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin within weeks or months after receiving a gadolinium-based contrast injection such as Omniscan and/or Magnevist. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a “woody” texture and are accompanied by burning, itching, or severe pain. NSF can also cause internal damage, such as fibrosis or scarring of the lungs, heart, liver, and musculature, which interferes

with functioning and may lead to death. NSF is a progressive disease for which there is no known cure.

38. GE and Bayer Defendant consistently failed to warn consumers, such as Decedent George Torres, and/or their healthcare providers that severe, even fatal, injuries could result when their dyes are administered to patients with renal insufficiency.

39. During the years that Defendants manufactured, marketed, and sold their respective products, there were numerous case reports, studies, assessments, papers, and other relevant experimental and clinical data that have described and/or demonstrated dissociation and transmetallation in connection with the use of certain gadolinium-based contrast agents. Despite this, the GE and Bayer Defendant failed to adequately revise their package inserts, Material Safety Data Sheets, and other product-related literature, and to conduct appropriate post-marketing communications in order to convey adequate warnings.

40. GE and Bayer Defendant repeatedly and consistently failed to advise consumers, such as Decedent George Torres, and/or their healthcare providers of the propensity of their products to undergo dissociation and transmetallation in vivo and of the causal relationship between certain gadolinium contrast dyes and the development of NSF in patients with renal insufficiency.

41. As a direct and proximate result of Defendants' wrongful conduct, Decedent George Torres suffered serious, progressive, permanent, incurable, and eventually fatal injuries, accompanied by significant pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment, disfigurement, and scarring.

42. Decedent George Torres and Plaintiffs have also incurred medical expenses and

other economic harm, as a direct and proximate result of gadolinium exposure from the gadolinium-based contrast agents in question.

VI. TOLLING OF THE STATUTE OF LIMITATIONS

43. The nature of Decedent George Torres' injuries was inherently difficult to discover. NSF is a relatively new and rare disease with early symptoms that are similar to several other conditions or diseases. Most, if not all NSF patients, go for months, or even years seeing multiple physicians, undergoing testing, being misdiagnosed, and receiving ineffective treatments before finally being properly diagnosed. Further, the relationship of Decedent George Torres' injuries to gadolinium exposure through a gadolinium-based contrast agent used during a magnetic resonance imaging was inherently difficult to discover. Consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff discovered, or by the exercise of reasonable diligence and intelligence should have discovered, that she may have a basis for an actionable claim.

44. Plaintiffs did not have knowledge of facts that would lead a reasonable person to investigate and discover Defendants' tortious conduct. Under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

45. Further, Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed from Plaintiff the nature of Decedent George Torres' injuries and the connection between said injuries and their gadolinium-based contrast agents.

46. Defendants are further estopped from asserting the statute of limitations defense pursuant to Judge Sandra Moss' Order in the Pennsylvania State Court Gadolinium Coordinated

actions where this case was originally filed, and subsequently dismissed pursuant to forum non conveniens.

**VII. COUNT ONE: STRICT PRODUCTS LIABILITY DEFECT DUE TO
INADEQUATE WARNING**

47. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

48. The Omniscan and/or Magnevist as manufactured and supplied by Defendants and/or their corporate predecessors were defective and unreasonably dangerous when they left the possession of Defendants in that they contained warnings insufficient to alert consumers, including Decedent George Torres, of the serious health risks, including, but not limited to NSF. Defendants and/or their corporate predecessors knew, or should have known, that the products created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers, including Decedent George Torres, and/or their healthcare providers of such risks. Defendants' failure to warn extended beyond the product's label and into other mediums available to Defendants, including but not limited to advertisements, person-to-person sales calls, medical journal articles, and medical conference presentations.

49. The Omniscan and/or Magnevist, as manufactured and supplied by Defendants and/or their corporate predecessors were defective due to inadequate warning or instruction because *after* Defendants and/or their corporate predecessors knew, or should have known, of the risk of serious bodily harm and death from the administration of their gadolinium-based contrast agents, Defendants and/or their corporate predecessors failed to provide adequate warnings to

consumers and/or their healthcare providers about the products, knowing the products could cause serious injury and death.

50. As a direct result of Defendants' and/or their corporate predecessors' failure to provide adequate warnings and instructions for their respective gadolinium-based contrast agents, as well as their failure to comply with federal standards, Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which Plaintiffs seeks just compensation herein.

VIII. COUNT TWO: STRICT PRODUCTS LIABILITY DESIGN DEFECT

51. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

52. Defendants and/or their corporate predecessors were manufacturers, designers, distributors, sellers, and/or suppliers of their respective gadolinium-based contrast agents.

53. The Omniscan and/or Magnevist manufactured and supplied by Defendants and/or their corporate predecessors were defective in design or formulation in that, when they left the hands of Defendants and/or their corporate predecessors, the foreseeable risks of serious harm posed by the products exceeded the benefits associated with their design or formulation, or they were more dangerous than an ordinary consumer would expect. Further, the products were not reasonably fit, suitable, or safe for their anticipated use, and safer, reasonable alternative designs existed and could have been utilized. Reasonably prudent manufacturers would not have placed these products in the stream of commerce with knowledge of these design flaws.

54. The foreseeable risks associated with the design or formulation of Omniscan

and/or Magnevist include, but are not limited to, the fact that their design or formulation is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

55. As a direct result of Defendants' and/or their corporate predecessors' defective design, as well as their failure to comply with federal standards, Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

**IX. COUNT THREE: STRICT PRODUCTS LIABILITY DEFECTIVE
MANUFACTURING**

56. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

57. Defendants and/or their corporate predecessors were manufacturers, designers, distributors, sellers, or suppliers of their respective gadolinium-based contrast agents.

58. The Omniscan and/or Magnevist manufactured, designed, sold, distributed, and/or placed into the stream of commerce by Defendants and/or their corporate predecessors were defective in their manufacture and construction when they left the hands of Defendants and/or their corporate predecessors in that they deviated from product specifications, posing a serious risk of injury and death.

59. At all times relevant herein, the gadolinium-based contrast agents were expected to reach, and did reach, consumers throughout the United States, including Decedent George Torres, without substantial change in the condition in which they were sold.

60. As a direct result of Defendants' and/or their corporate predecessors' defective manufacturing, as well as their failure to comply with federal standards, Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

X. COUNT FOUR: STRICT PRODUCTS LIABILITY

DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS

61. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

62. Defendants and/or their corporate predecessors were manufacturers, designers, distributors, sellers, and/or suppliers of their respective gadolinium-based contrast agents and made representations regarding the character and/or quality of their respective products.

63. The gadolinium-based contrast agents manufactured and supplied by Defendants and/or their corporate predecessors were defective in that, when they left the hands of Defendants and/or their corporate predecessors, they did not conform to representations made concerning the products.

64. Decedent George Torres and/or his healthcare providers justifiably relied upon Defendants' and/or their corporate predecessors' representations regarding their respective gadolinium-based contrast agents at the time they were administered.

65. As a direct and proximate result of Decedent George Torres and/or his healthcare providers' reliance on said representations, as well as Defendants' and/or their corporate predecessors' failure to comply with federal standards, Decedent George Torres suffered

catastrophic personal injuries, economic harm, and legal damages for which Plaintiffs seeks just compensation herein.

XI: COUNT FIVE: STRICT PRODUCTS LIABILITY DEFECT

DUE TO FAILURE TO ADEQUATELY TEST

66. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

67. Defendants and/or their corporate predecessors were manufacturers, designers, distributors, sellers, and/or suppliers of their respective gadolinium-based contrast agents. Defendants and/or their corporate predecessors advised consumers and the medical community that their respective products Omniscan and/or Magnevist were safe for use.

68. Defendants failed to adequately test their respective products for use by consumers with renal insufficiency. Omniscan and/or Magnevist as designed, marketed, distributed, and sold by Defendants, were unreasonably dangerous and not suitable for use by consumers with renal insufficiency in that they posed serious health risks, including, but not limited to NSF. If Defendants had adequately tested their respective products, and had disclosed the results to consumers and/or the medical community, Decedent George Torres would not have been administered the gadolinium-based contrast agents in question.

69. As a direct and proximate result of Defendants' inadequate testing of the safety of Omniscan and/or Magnevist Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

XII. COUNT SIX: STRICT LIABILITY IN TORT

70. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

71. At all times material hereto, Defendants used and controlled toxic gadolinium for injection in humans.

72. Gadolinium is highly toxic, inherently dangerous, and ultrahazardous to humans. Defendants allowed and directed that toxic gadolinium be used and injected in humans.

73. As a direct and proximate result of Defendants' use and control of toxic gadolinium, Decedent George Torres was injected with toxic gadolinium and Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

74. Defendants are strictly liable for Decedent George Torres' personal injuries, damages, and losses.

XIII: COUNT SEVEN: NEGLIGENCE

75. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

76. Defendants and/or their corporate predecessors had a duty to exercise ordinary or reasonable care in the design, manufacture, testing, promotion, marketing, sale, and/or distribution of their respective gadolinium-based contrast agents into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

77. Alternatively, because gadolinium is highly toxic, inherently dangerous, and

ultrahazardous to humans, Defendants had a duty to exercise the highest possible degree of care in the design, manufacture, testing, promotion, marketing, sale, and/or distribution of their respective gadolinium-based contrast agents.

78. Defendants and/or their corporate predecessors failed to exercise due care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of their respective gadolinium-based contrast agents into interstate commerce in that Defendants and/or their corporate predecessors knew, or should have known, that their products caused significant harm or death and were not safe for administration to consumers.

79. Defendants and/or their corporate predecessors also failed to exercise due care in the labeling of their respective gadolinium-based contrast agents and failed to issue to consumers and/or their healthcare providers adequate warnings as to the risk of serious bodily injury or death resulting from their use.

80. Despite the fact that Defendants and/or their corporate predecessors knew, or should have known, that their respective gadolinium-based contrast agents posed a serious risk of bodily harm to consumers, Defendants and/or their corporate predecessors continued to manufacture and market their respective products for administration to magnetic resonance imaging and arteriography patients with renal insufficiency.

81. Defendants and/or their corporate predecessors knew, or should have known, that consumers, such as Decedent George Torres, would foreseeably suffer injury as a result of Defendants' and/or their corporate predecessors' failure to exercise due care as described above.

82. As a direct and proximate result of Defendants' and/or their corporate

predecessors' negligent design, testing, manufacturing, labeling, promoting, marketing, distributing, and selling, as well as their failure to comply with federal standards, Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

XIV. COUNT EIGHT: BREACH OF EXPRESS WARRANTY

83. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

84. Defendants and/or their corporate predecessors expressly warranted that their respective gadolinium-based contrast agents were safe and effective for magnetic resonance studies.

85. The respective gadolinium-based contrast agents manufactured and sold by Defendants and/or their corporate predecessors did not conform to these representations because they caused serious injury and death to consumers, such as George Torres, when injected in routinely administered dosages.

86. As a direct and proximate result of Defendants' and/or their corporate predecessors' breach of express warranty, as well as their failure to comply with federal standards, Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

XV. COUNT NINE: BREACH OF IMPLIED WARRANTIES

87. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

88. At the time Omniscan and/or Magnevist were promoted, marketed, distributed, and/or sold by Defendants and/or their corporate predecessors, Defendants knew of the use for which they were intended and impliedly warranted their respective products to be of merchantable quality and safe and fit for such use.

89. Decedent George Torres reasonably relied upon the skill, superior knowledge, and/or judgment of Defendants as to whether the product was of merchantable quality and safe and fit for its intended use.

90. Contrary to Defendants' implied warranties, the gadolinium-based contrast agents used by Decedent George Torres were not of merchantable quality and were not safe or fit for their intended use because the products were unreasonably dangerous as described herein.

91. As a direct and proximate result of Defendants' and/or their corporate predecessors' breach of implied warranties, as well as their failure to comply with federal standards, Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

XVI. COUNT TEN: NEGLIGENT MISREPRESENTATION

92. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

93. The GE and Bayer Defendant and/or their corporate predecessors, in the course of their business, supplied false information for the guidance of consumers, including Decedent

George Torres, and his healthcare providers. The false representation was that their respective gadolinium-based contrast agents were safe, would not adversely affect the health of consumers, such as George Torres, and that their labeling, promotions, and marketing fully described all known risks of the products.

94. The GE and Bayer Defendant and/or their corporate predecessors had actual knowledge based upon studies, published reports and clinical experience that their respective gadolinium-based contrast agents created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information and did not exercise reasonable care or competence in obtaining or communicating the information.

95. The GE and Bayer Defendant and/or their corporate predecessors intentionally or negligently omitted this information in the product labeling, promotions, and marketing and instead labeled, promoted, and marketed their respective products as safe in order to avoid losses and sustain profits in their sales to consumers.

96. Decedent George Torres and his healthcare providers reasonably and/or justifiably relied upon Defendants' and/or their corporate predecessors' misrepresentations in their labeling, marketing, and promotions concerning the serious risks posed by said products.

97. As a direct and proximate result of Defendants' and/or their corporate predecessors' misrepresentations, as well as their failure to comply with federal standards, Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

XVII. COUNT ELEVEN: FRAUD OR FRAUDULENT MISREPRESENTATION

98. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

99. The GE and Bayer Defendant made material, false, and misleading representations to consumers, including Plaintiff, his healthcare providers and the Food and Drug Administration ("FDA") that their respective gadolinium-based contrast agents were safe, would not adversely affect the health of consumers, such as George Torres, and that their labeling, promotions, and marketing fully described all known risks of the products.

100. When Defendants made the representation, they knew it was false, or they made the representation recklessly, as a positive assertion, and without knowledge of its truth. The respective Defendants knew, based upon studies, published reports and clinical experience that Omniscan and/or Magnevist created an unreasonable risk of serious bodily injury and death to consumers, such as George Torres.

101. Defendants knowingly and intentionally concealed and withheld from consumers, including Decedent George Torres and his healthcare providers, the true facts that their respective products are unsafe for people with renal insufficiency. Defendants had a duty to disclose said information because they had superior knowledge of these facts that were material to consumers, including George Torres, his healthcare providers and the FDA in deciding whether or not to use the products.

102. Defendants made the representation with the intent that consumers, such as Decedent George Torres, and his healthcare providers and the FDA, would act on it, thereby increasing their sales.

103. Decedent George Torres and his healthcare providers and the FDA relied on the

false representations and intentional concealment of true facts, and as a direct result, Decedent George Torres suffered catastrophic personal injuries, economic harm, and legal damages for which plaintiff seeks just compensation herein.

XVIII. COUNT TWELVE: WRONGFUL DEATH

104. Plaintiffs reallege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety. George Torres, deceased, left his estate as surviving beneficiary entitled to assert all claims under the applicable state law for wrongful death and survival actions.

105. The negligence and carelessness of Defendants, as outlined above, created the injuries and losses for which the Plaintiffs, including Plaintiff Cindy Torres, as duly appointed administrator of George Torres, claim damages herein.

106. At all times pertinent hereto, Defendants had actual or constructive knowledge of the defects or procedures as referenced in the proceeding paragraphs, which created the injuries and losses for which the Plaintiffs, including Plaintiffs Cindy Torres both individually and as duly appointed administrator of George Torres, George Scott Torres, individually, Kevin Torres, individually, Timothy Ryan Torres, individually, claim damages herein.

107. As a proximate consequence of the wrongful death of decedent, George Torres, Decedents' survivors and heirs at law have suffered, will continue to suffer forever, and claim damages for losses including but not limited to the following:

- a. Medical, funeral, burial, and administrative expenses;
- b. Loss of service, society, comfort, maintenance, advice, earning capacity,

guidance, and tutelage which decedent would have provided for the remainder of decedent's natural life; and

- c. Such other pecuniary losses recoverable under the Wrongful Death Act and applicable state law.

WHEREFORE, Plaintiffs, including Plaintiffs Cindy Torres both individually and as duly appointed administrator of George Torres, George Scott Torres, individually, Kevin Torres, individually, Timothy Ryan Torres, individually, demand judgment against Defendants individually, jointly, severally for any and all damages (including, but not limited to severe physical pain and suffering, mental anguish, severe anxiety, loss of life's pleasures, loss of enjoyment of life, death, and loss of future earning capacity, future earnings, and income) as well as punitive damages, cognizable in accordance with the laws of the applicable state, together with interest, cost of suit and attorneys' fees as allowed by law.

XIX. COUNT THIRTEEN: SURVIVAL ACTION

108. Plaintiffs reallege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

109. George Torres, deceased, left his estate as surviving beneficiary entitled to assert all claims under the applicable state law for wrongful death and survival actions.

110. The negligence and carelessness of Defendants, as outlined above, created the injuries and losses for which Plaintiffs claim damages herein.

111. At all times pertinent hereto, Defendants had actual or constructive knowledge of

the defects or procedures as referenced in the proceeding paragraphs, which created the injuries and losses for which the Plaintiffs claim damages herein.

112. As a proximate consequence of defendants' negligence, George Torres suffered severe physical pain and suffering, mental anguish, severe anxiety, loss of life's pleasures, loss of enjoyment of life until the time of her death for which George Torres' heirs are entitled to seek compensation for on her behalf.

WHEREFORE, Plaintiffs demand judgment against Defendants individually, jointly, severally for any and all damages (including, but not limited to, severe physical pain and suffering, mental anguish, severe anxiety, loss of life's pleasures, loss of enjoyment of life, death, and loss of future earning capacity, future earnings, and income) as well as punitive damages, cognizable in accordance with the laws of the applicable state, together with interest, cost of suit and attorneys' fees as allowed by law.

XX. JURY DEMAND

113. Plaintiffs hereby demands a trial by jury on all issues so triable.

XXI. PRAYER

114. WHEREFORE, Plaintiff prays for judgment against Defendants and for relief as follows:

- a. Compensatory damages experienced in the past and in reasonable probability to be experienced in the future as a direct and proximate result of

Defendants' wrongful conduct described herein, in an amount in excess of the jurisdictional amount provided by law, including, but not limited to physical pain and suffering; mental anguish, emotional distress; physical impairment or disability; loss of enjoyment of life; physical disfigurement, scarring; reasonable and necessary medical expenses; lost wages or earnings, if any; and damage to wage-earning capacity, if any;

- b. Punitive damages as awarded by the jury;
- c. Prejudgment and post-judgment interest;
- d. Reasonable attorneys' fees;
- e. Filing fees and reasonable costs of court; and
- f. Such other and further legal and equitable relief as this Honorable Court may deem necessary, just, and proper.

DATED: June 14, 2010

Respectfully Submitted,

/ s / Jason E. Ochs
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